

**I. Remarks**

A) Claims 12-31 are currently pending in the instant application. Claim 22 has been amended to recite "adeno-associated virus". Support for this amendment is found throughout the instant specification, the originally filed claims, and at page 9, lines 13-15. Accordingly, the amendment does not add new matter. Its entry is respectfully requested.

B) At the Examiner's earliest convenience, Applicant respectfully requests that he return an initialed copy of the Information Disclosure Statement filed by Applicant with the Office on October 27, 2007.

**II. Claim rejections under Non-Statutory Obviousness-Type Double Patenting**

Claims 12-31 stand rejected based on the ground of non-statutory obviousness-type double patenting as being allegedly unpatentable over claims 1-4 and 6-11 of U.S. Patent No. 6,667,174. Applicant has submitted with this response a terminal disclaimer that renders this rejection moot. In making this disclaimer, the Assignee of the instant application makes it with the understanding that this disclaimer serves the statutory function of removing the rejection of double patenting<sup>1</sup> and "raises neither presumption nor estoppel on the merits of the rejection"<sup>2</sup>. Accordingly, Applicant respectfully requests withdrawal of this rejection.

**III. Claim objections under 37 CFR § 1.75**

Upon the allowance of claim 12, claim 22 will be objected to under 37 CFR § 1.75 as being a substantial duplicate of claim 12. Claim 22 has been amended to recite "adeno-associated virus". Accordingly, the amendment renders this provisional objection moot.

**IV. Claim rejections under 35 U.S.C. § 112m second paragraph**

Claims 23-29 stand rejected based on the ground of non-statutory obviousness-type double patenting as being allegedly indefinite for failing to particularly pointing out and distinctly claiming the subject matter which Applicant regards as the invention. In particular, the instant claims depend from claim 22, which recite "adenovirus", whereas claims 23-29 refer to "adeno-associated virus". Thus, claims 23-29 allegedly lack proper antecedent basis.

With this response, Applicant has amended claim 22 to recite adeno-associated virus and provide proper antecedent basis for the instant claims. Accordingly, this rejection is moot and Applicant respectfully requests its withdrawal.

---

<sup>1</sup> Quad Environmental Technologies Corp. v. Union Sanitary Dist., 946 F.2d 870, 874 (Fed. Cir. 1991)

<sup>2</sup> *Id.*

**V. Claim Amendments under 37 C.F.R. § 1.121**

1-11. (Canceled)

12. (Previously presented) An adenovirus vector comprising a recombinant expression vector comprising one or more enhancers linked to the 5' end of a ubiquitin promoter operably linked to a DNA sequence encoding a therapeutic transgene.

13. (Previously presented) The adenovirus vector of claim 12, wherein the ubiquitin promoter is isolated from a gene selected from the group consisting of human ubiquitin A, ubiquitin B, and ubiquitin C.

14. (Previously presented) The adenovirus vector of claim 12, wherein the enhancer is selected from the group consisting of cytomegalovirus (CMV) enhancer, an elongation factor 1-alpha enhancer, endothelial enhancers, and liver-specific enhancers.

15. (Previously presented) The adenovirus vector of claim 14, wherein the enhancer is a CMV enhancer.

16. (Previously presented) The adenovirus vector of claim 14, wherein the ubiquitin promoter is isolated from human ubiquitin B.

17. (Previously presented) The adenovirus vector of claim 12, wherein the therapeutic gene is selected from the group consisting of Factor VIIa, Factor VIII, and Factor IX.

18. (Previously presented) The adenovirus vector of claim 12, wherein the therapeutic gene is selected from the group consisting of glucocerebrosidase, alpha-galactosidase, acid alpha-glucosidase, alpha-n-acetylgalactosaminidase, acid sphingomyelinase, and alpha-iduronidase.

19. (Previously presented) The adenovirus vector of claim 12, wherein the therapeutic gene is selected from the group consisting of CFTR, dystrophin, and alpha-1-antitrypsin.

20. (Previously presented) An adenovirus vector comprising a recombinant expression vector comprising a CMV enhancer linked to the 5' end of a promoter isolated from human ubiquitin B operably linked to a DNA sequence encoding alpha-galactosidase.

21. (Previously presented) An adenovirus vector comprising a recombinant expression vector comprising a CMV enhancer linked to the 5' end of a promoter isolated from human ubiquitin B operably linked to a DNA sequence encoding glucocerebrosidase.

22. (Currently amended) An adenovirus adeno-associated virus vector comprising a recombinant expression vector comprising one or more enhancers linked to the 5' end of a ubiquitin promoter operably linked to a DNA sequence encoding a therapeutic transgene.

23. (Previously presented) The adeno-associated virus vector of claim 22, wherein the ubiquitin promoter is isolated from a gene selected from the group consisting of human ubiquitin A, ubiquitin B, and ubiquitin C.

24. (Previously presented) The adeno-associated virus vector of claim 22, wherein the enhancer is selected from the group consisting of cytomegalovirus (CMV) enhancer, an elongation factor 1-alpha enhancer, endothelial enhancers, and liver-specific enhancers.

25. (Previously presented) The adeno-associated virus vector of claim 24, wherein the enhancer is a CMV enhancer.

26. (Previously presented) The adeno-associated virus vector of claim 24, wherein the ubiquitin promoter is isolated from human ubiquitin B.

27. (Previously presented) The adeno-associated vector of claim 22, wherein the therapeutic gene is selected from the group consisting of Factor VIIa, Factor VIII, and Factor IX.

28. (Previously presented) The adeno-associated vector of claim 22, wherein the therapeutic gene is selected from the group consisting of glucocerebrosidase, alpha-galactosidase, acid alpha-glucosidase, alpha-n-acetylgalactosaminidase, acid sphingomyelinase, and alpha-iduronidase.

29. (Previously presented) The adeno-associated vector of claim 22, wherein the therapeutic gene is selected from the group consisting of CFTR, dystrophin, and alpha-1-antitrypsin.

30. (Previously presented) An adeno-associated vector comprising a recombinant expression vector comprising a CMV enhancer linked to the 5' end of a promoter isolated from human ubiquitin B operably linked to a DNA sequence encoding alpha-galactosidase.

31. (Previously presented) An adeno-associated vector comprising a recombinant expression vector comprising a CMV enhancer linked to the 5' end of a promoter isolated from human ubiquitin B operably linked to a DNA sequence encoding glucocerebrosidase.

**VI. Conclusion**

No fee is deemed necessary in connection with the filing of this communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

4/16/08  
\_\_\_\_\_  
Date

Respectfully submitted,

  
\_\_\_\_\_  
Jennifer D. Tousignant  
Attorney for Applicants  
Registration No. 54,498  
Telephone: (508) 270-2499  
Facsimile: (508) 872-5415

GENZYME CORPORATION  
15 Pleasant Street Connector  
P.O. Box 9322  
Framingham, Massachusetts 01701-9322